



*HIP & KNEE RECONSTRUCTIVE CENTER • CENTER FOR SPINAL DISORDERS • FOOT & ANKLE CENTER • SPORTS MEDICINE*  
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Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Document No.: **97N-484S**

To Whom It May Concern:

It has been brought to my attention that there are proposed FDA Regulation changes that would allow the FDA to regulate some types of bone allograft as medical devices. Given that bone banks do not have the resources or expertise to satisfy the FDA's requirements, such as sponsoring clinical trials and submitting in-depth regulatory documents, this may lead to a curtailed supply of bone products which we depend on for treating patients. The potential implications of the proposed FDA regulation changes are significant and of deep concern.

Thank you for your consideration.

Sincerely,

Richard V. Abdo, M.D.

RVA:dgh

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